

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

DMB

Display Date	2/16/00 @ 4:19pm
Publication Date	2/22/00
Certifier	SN Reese

**Food and Drug Administration** 0105 '00 FEB 17 A9:03

**Food and Drug Administration/Industry Exchange Workshop on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of workshop.

---

**SUMMARY:** The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Central Region Small Business Office, and the Northeast Region Small Business Office, in cooperation with the International Society for Pharmaceutical Engineering (ISPE) is announcing the following workshops: FDA/Industry Exchange Workshops on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshops are intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

*Date and Time:* See Table 1 following the "Location" section of this document.

*Location:* See Table 1 below.

TABLE 1

Workshop Address	Date and Local Time	FDA Contact Person
Newark Airport Marriot, Newark International Airport, Newark, NJ 07114, 1-800-882-1037, FAX: 973-623-7618	Monday, March 20, 2000, from 9 a.m. to 5 p.m.	Marie T. Falcone
Chicago Marriott Schaumburg, 50 North Martingale Rd., Schaumburg, IL 60173, 847-240-0100, FAX: 847-240-2388	Monday, April 10, 2000, from 9 a.m. to 5 p.m.	Do.
Providence Marriott, One Ohms St., Providence, RI 02904, 1-800-937-7768, FAX: 401-861-3550	Thursday, May 4, 2000, from 9 a.m. to 5 p.m.	Do.

Persons needing hotel rooms should mention that they are attending the ISPE, FDA/SUPAC workshop.

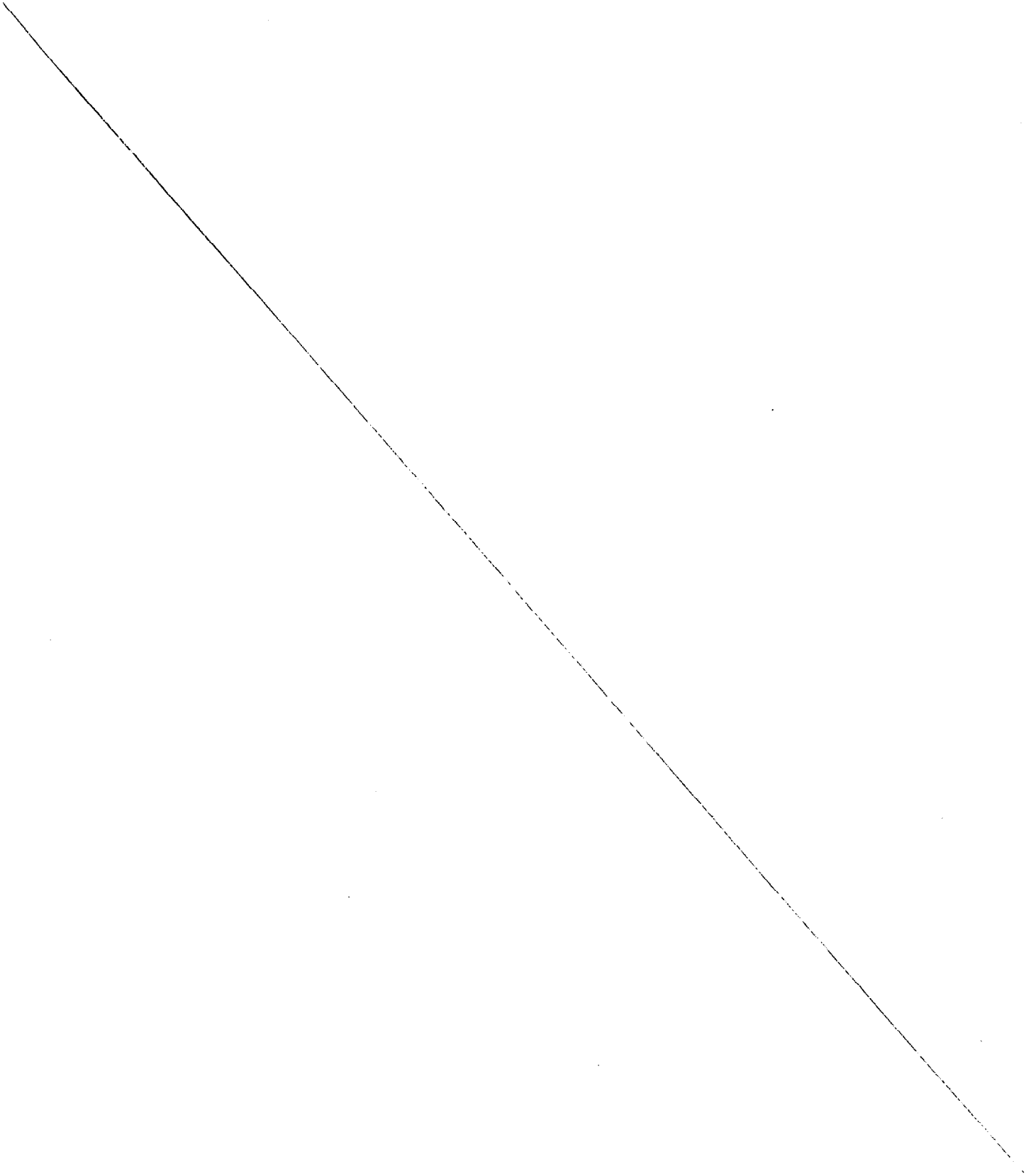
*Contact:* Marie T. Falcone, Industry and Small Business Representative, FDA, rm. 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106, 215-597-2120, ext. 4003, e-mail: mfalcone@ora.fda.gov.

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number), along with a \$295 check (member) or \$450 (nonmembers) (which will cover refreshments, lunch, and materials) made payable to ISPE, 3816 W. Linebaugh Ave., suite 412, Tampa, FL 33624, 813-960-2105, or visit the ISPE at the Internet at <http://www.ispe.org>. Registrations are due 1 week prior to the start of each course. Space is limited, therefore, interested parties are encouraged to register early. Limited on-site registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact ISPE at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The workshops further implement the FDA Plan for Statutory Compliance (developed under Section 406 of the FDA Modernization Act (21 U.S.C. 393)) by working more closely with stakeholders, maximizing the availability of, and clarifying information about the process for review and submissions, and ensuring access to needed scientific and technical expertise.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage

forms, and semisolid-topical dosage forms; (3) bulk actives postapproval changes; (4) postapproval changes sterile aqueous solutions; (5) FDA field staff's involvement in SUPAC; (6) description and use of the equipment addenda to SUPAC; and (7) facts, figures, and future directions.



The workshop also complies with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121)<sup>which</sup> that requires outreach activities by government agencies directed to small businesses.

Dated: February 16, 2000



William K. Hubbard  
Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

